K112702

MAR 2 9 2012

510(k) Summary
For
Imperial Surgical Ltd. BLANKET and SOLUTION WARMING CABINETS

September 14, 2011

Manufactured by:	Imperial Surgical Ltd.
Contact Name:	Suzy Bairos, Vice President
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1. **Device Name/Codes**

Device Proprietary Name:Imperial Surgical Blanket and Solution Warming Cabinets

Common/Usual Name: Warming Cabinets

Classification Name: Warmer, Thermal, Infusion Fluid
Classification Code: LGZ

2. **Predicate Device**

Steris Amsco Warming Cabinet (K092823, December 12, 2009)
Enthermics EC-7701 Fluid Warming Cabinet, K993797, January 20, 2000

3. **Description of Device**

The Imperial Surgical Ltd. Blanket and Solution Warming Cabinets are designed to store and warm blankets, hospital linens, irrigation fluids and/or injection fluids in accordance with the recommended warming temperatures and storage time guidelines provided by the manufacturers of such products

The subject device is available with either single compartment or double compartment cabinets, all designed to ensure maximum storage capability. The 7000 series are made of 18 gauge stainless steel with the doors and shelves made of 20 gauge stainless steel. The 8000 series are of a similar design to the 7000 series, however the stainless steel doors have an inset double pane tempered glass to allow interior cabinet viewing. The small 9000 series are made of powder coated steel, and the doors have an inset Plexiglas also to allow interior cabinet viewing.

4. **Intended Use**

The Imperial Surgical Ltd. Blanket and Solution Warming Cabinets are designed to store and warm blankets, hospital linens, irrigation fluids and/or injection fluids in accordance with the recommended warming temperatures and storage time guidelines provided by the manufacturers of such products

5. Description of Safety and Substantial Equivalence

The Imperial Surgical Ltd. Blanket and Solution Warming Cabinets are substantially equivalent to the two predicate devices in all material respects. Please refer to the table below comparing the technological characteristics of the proposed Imperial Surgical Blanket and Solution Warming Cabinets to the predicate devices.

Summary of the Proposed Device and Predicate Devices Technological Characteristics

Features	Imperial Surgical Ltd. Blanket and Solution Warming Cabinets	Amsco Warming Cabinet (K092823)	EC-7701 Fluid Warming Cabinet (K993797)
Intended Use	The Imperial Surgical Ltd. Blanket and Solution Warming Cabinets are designed to store and warm blankets, hospital linens, irrigation fluids and/or injection fluids in accordance with the recommended warming temperatures and storage time guidelines provided by the manufacturers of such products	Amsco Warming Cabinet is for heating flasked solutions, blankets and similar clinical articles.	The Enthermics Medical Systems EC-7701 Fluid Warming Cabinet is designed for safely store and warm irrigation fluids or injection fluids in accordance with the recommended warming temperatures and storage times stated in the fluid manufacturer's labeling.
Heating System	Convection Electric heating element with circulating fan	Steam heat or Electric heater blanket and fan blower (convection heating)	Fully insulated electrothermal cable array (Convection heating) Usually radiant heating
Unit Configuration	Single / dual	Single/Dual	Single
Unit Depth	22" or 28" for table top and full size cabinets. 16" depth on count top model.	18" or 24"	34"
Model	Wall or Counter	Wall or Counter	Wall
Interior and Exterior Surfaces	Stainless Steel interior and exterior on table top and full size models. Counter top model made with baked on powder coated steel outer shell with Stainless Steel interior.	Stainless Steel	Stainless Steel
Installation	Free standing or recessed	Open-Mounted or Recessed	Free-standing (mobile) or Recessed

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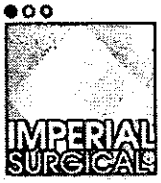

TRADITIONAL 510(k) PREMARKET SUBMISSION
IMPERIAL SURGICAL LTD. BLANKET and SOLUTION WARMING CABINETS

Features	Imperial Surgical Ltd. Blanket and Solution Warming Cabinets	Amsco Warming Cabinet (K092823)	EC-7701 Fluid Warming Cabinet (K993797)
Door	Stainless steel or double pane Glass set in stainless steel frame on table top and full size models. Counter top model has Plexiglas mounted on to anodized aluminum door frame.	Stainless Steel	Stainless Steel (Glass)
Cabinet Storage Capacity	Dual compartment and full size cabinets equipped with 3 stainless steel perforated shelves Table top model equipped with 1 stainless steel perforated shelf	Dual Compartment Model- Two shelves: 15 flasks -18" upper 45 flasks -18" lower 20 flasks -24" upper 60 flasks -24" lower Single Compartment Model- One Shelf 15 flasks -18" 20 Flasks - 24"	The cabinet is equipped with three (3) white epoxy-coated wire baskets, each with 24 liter capacity.
Cabinet Volume	Dual compartment capacity 18.1 cu ft overall (4.3 cu ft upper - 13.8 cu ft lower) Single compartment full size capacity 19.8 cu t Single compartment shallow depth design capacity 14.6 cu ft Table top model capacity 7.5 cu ft Table top shallow design capacity 5.2 cu ft Counter top version has capacity of 2.0 cu ft (approx)	18" upper chamber - 3.1 cu ft 24" upper chamber - 4.2 cu ft 18" lower chamber - 8.9 cu ft 24" lower chamber - 12 cu ft	Single compartment Apprx 7.8 cu ft internal capacity
Controls	Electronic temp controller with LED display. Illuminated power switch/breaker (red) Amber neon indictor for Element on Red neon indictor for trouble	Thermostat/power switch/fuse with indicating light/color coded temperature selector.	Electronic control consists of 4 digit LED display, on/off keys, integrated lock feature and a series of prompt sequence indicators.
Software	N/A	N/A	Not applicable

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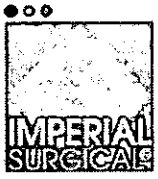

TRADITIONAL 510(k) PREMARKET SUBMISSION
IMPERIAL SURGICAL LTD. BLANKET and SOLUTION WARMING CABINETS

Features	Imperial Surgical Ltd. Blanket and Solution Warming Cabinets	Amsco Warming Cabinet (K092823)	EC-7701 Fluid Warming Cabinet (K993797)
Temperature Selection Range	Can be factory programmed for Blankets: 30°C to 71°C (86°F to 160°F) For Irrigation Fluids: 30°C to 66°C (86°F to 150°F) For Injection Fluids: 30°C to 40°C (86°F to 104°F) Must be specified at time of ordering.	95°F to 150°F (35°C to 65°C)	90°F to (32°C) to 150°F to (66°C)
Temperature Lock	Settings are factory set and locked. The device can be unlocked in the field and user can change settings if they wish to.	N/A	The device allows the user to "lock" the mode (IRR or INJ) and temperature setting controls.
Door Lock	Not available	Available by SSQ (Special Sales Quote) only.	Available as an option
Over Temperature Alarm Point	Visual alarm if chamber temperature exceeds 6°C above set temperature. Internal sensor shuts off heating elements when over temperature occurs	Visual alarm if unit has a chamber temperature greater than 12°F above set temperature. In the event of an over temp condition, sensors automatically turns off the heather (s).	Visual and audible alarm if unit has a chamber temperature greater than 10°F (5.5°C) above set temperature. In the event f an over temp condition, the heating system shuts down.
Voltage Requirements	120VAC 60Hz	Electric Model: 110/120 Vac, 220/240 Vac nominal, 50/60 HZ. Steam Model: 120 Vac single phase.	125 Vac, 60 Hz, 1 ph

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6. Substantial Equivalent Assessment of non-clinical performance data.

The Imperial Surgical Ltd. Blanket and Solution Warming Cabinets have been tested to confirm they are safe and effective for their intended use. The following safety and functional tests have been performed:

Electrical safety is demonstrated as each unit is field certified by CSA International using CSA Standard(s) C22.2 No(s). 0,0.4 as a guide and SPE-1000, UL1262, US Field Evaluation.

Performance testing has been conducted to evaluate the following:

- accuracy of the temperature controller
- even distribution of heat throughout the cabinet with limited temperature variance, and with multiple temperature readings within the accepted temperature variance of +/- 1.5°C.
- how quickly the cabinet will reach the desired temperature setting from a cold start.
- the recovery time required when the cabinet door is opened repeatedly for the temperature to return to the desired setting.
- time required for the cabinet to achieve the desired temperature setting loaded to 3/4 of its capacity (typical load expected during operation).

All tests met the expected specifications for the device. It is concluded that the electrical safety and performance testing conducted support the safety and effectiveness of the Imperial Surgical Ltd. Blanket and Solution Warming Cabinets.

7. Conclusion

Based on the information provided in this 510(k) premarket notification, the Imperial Surgical Ltd. Blanket and Solution Warming Cabinets are substantially equivalent in terms of safety and effectiveness to the predicate devices identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Imperial Surgical Limited
C/O Ms. Kathryn Ronalds
Associate Director, Regulatory Affairs (Devices)
CanReg Incorporation
4 Innovation Drive
Dundas
CANADA L9H 7P3

MAR 2 9 2012

Re: K112702
Trade/Device Name: Blanket and Solution Warming Cabinets
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LGZ
Dated: March 21, 2012
Received: March 22, 2012

Dear Ms. Ronalds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112702

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Blanket and Solution Warming Cabinets

Indications for Use:

The Imperial Surgical Ltd. Blanket and Solution Warming Cabinets are designed to store and warm blankets, hospital linens, irrigation fluids and/or injection fluids in accordance with the recommended warming temperatures and storage time guidelines provided by the manufacturers of such products.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___√___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C Chapman 3/28/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112702